

AMENDED IN SENATE APRIL 21, 2004

AMENDED IN SENATE APRIL 12, 2004

SENATE BILL

No. 1765

Introduced by Senator Sher
(Coauthors: Senators Chesbro and Kuehl)

February 20, 2004

An act to add Chapter 8 (commencing with Section 119400) to Part 15 of Division 104 of the Health and Safety Code, relating to pharmaceutical marketing.

LEGISLATIVE COUNSEL'S DIGEST

SB 1765, as amended, Sher. Pharmaceuticals: marketing practices.

The Sherman Food, Drug, and Cosmetic Law regulates the packaging, labeling, and advertising of drugs and devices.

~~This bill would prohibit a pharmaceutical company, as defined, from giving gifts to medical or health professionals, with exceptions for drug samples, educational materials, and low-cost items primarily associated with a health care professional's practice. The bill would limit the total value of gifts received by a medical or health professional to \$340 in any calendar year.~~

This bill would require a pharmaceutical company to adopt and update a Comprehensive Compliance Program, that is in accordance with a related federal government publication. The bill would require the Comprehensive Compliance Program to include, among other provisions, policies on interactions with health care professionals and limits on gifts and incentives to medical or health professionals, ~~as imposed by the bill.~~ *The bill would require each pharmaceutical company to establish explicitly in its Comprehensive Compliance*

Program a specific annual dollar limit on gifts, promotional materials, or items or activities that the pharmaceutical company may give or otherwise provide to an individual medical or health care professional, with certain exemptions.

This bill would require a pharmaceutical company to (1) annually ~~acknowledge~~ *certify*, in writing, compliance with the Comprehensive Compliance Program and the bill, ~~and~~ (2) make its Comprehensive Compliance Program and written acknowledgment of compliance available for public inspection upon request to the public on its Web site, and (3) provide a toll-free telephone number where a copy or copies of the Comprehensive Compliance Program and written certification of compliance may be obtained.

This bill would provide that it is not to be construed to create a standard for a pharmaceutical company that is less restrictive than any otherwise applicable provision of existing law.

The bill would require its provisions to become operative on July 1, 2005.

Vote: majority. Appropriation: no. Fiscal committee: no.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature finds and declares all of the
2 following:

3 (a) The trade association known as the Pharmaceutical
4 Research and Manufacturers of America (PhRMA) has developed
5 voluntary guidelines for pharmaceutical companies that pertain to
6 gifts and financial incentives provided to doctors.

7 (b) The Office of Inspector General (OIG) within the United
8 States Department of Health and Human Services has developed
9 recommendations for pharmaceutical companies that pertain to
10 gifts, financial incentives, and other matters relating to the
11 development, manufacturing, marketing, and sales of
12 pharmaceutical products.

13 (c) The PhRMA guidelines state, “We are also concerned that
14 our interactions with healthcare professionals not be perceived as
15 inappropriate by patients or the public at large.”

16 (d) The OIG guidelines state, “A comprehensive compliance
17 program provides a mechanism that addresses the public and
18 private sectors’ mutual goals of reducing fraud and abuse;

enhancing health care provider operational functions; improving the quality of health care services; and reducing the cost of health care.”

(e) It is therefore the intent of the Legislature in enacting this act to achieve the goals expressed in both the PhRMA voluntary guidelines and the OIG voluntary guidelines and to ensure greater adherence by pharmaceutical companies to both sets of existing guidelines by requiring pharmaceutical companies to adopt policies that ensure compliance with those guidelines.

SEC. 2. Chapter 8 (commencing with Section 119400) is added to Part 15 of Division 104 of the Health and Safety Code, to read:

CHAPTER 8. DRUG MARKETING PRACTICES

119400. The following definitions shall apply for purposes of this chapter:

(a) “Dangerous drug” means any drug that is unsafe for self-use and includes either of the following:

(1) Any drug that bears the legend “Caution: federal law prohibits dispensing without prescription,” “Rx only,” or words of similar import.

(2) Any drug or device that, pursuant to federal or state law, may be dispensed only by prescription, or that is furnished pursuant to Section 4006 of the Business and Professions Code. “Dangerous drug” does not include labeled veterinary drugs.

(b) “Medical or health professional” means any of the following:

(1) A person licensed by state law to prescribe drugs for human patients.

(2) A medical student.

(3) A member of a drug formulary committee.

(c) “Pharmaceutical company” means an entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of dangerous drugs, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis. “Pharmaceutical company” also means an entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of dangerous drugs.

1 “Pharmaceutical company” also includes a person who engages
2 in pharmaceutical detailing, promotional activities, or other
3 marketing of a dangerous drug in this state on behalf of a
4 pharmaceutical company. “Pharmaceutical company” does not
5 include a licensed pharmacist.

6 119402. (a) Every pharmaceutical company shall adopt a
7 Comprehensive Compliance Program that is in accordance with
8 the April 2003 publication “Compliance Program Guidance for
9 Pharmaceutical Manufacturers,” which was developed by the
10 United States Department of Health and Human Services Office
11 of Inspector General (OIG). A pharmaceutical company shall
12 make conforming changes to its Comprehensive Compliance
13 Program within six months of any update or revision to the
14 “Compliance Program Guidance for Pharmaceutical
15 Manufacturers.”

16 (b) Every pharmaceutical company shall include in its
17 Comprehensive Compliance Program policies for compliance
18 with the Pharmaceutical Research and Manufacturers of America
19 (PhRMA) “Code on Interactions with Health Care
20 Professionals,” dated July 1, 2002. The pharmaceutical company
21 shall make conforming changes to its Comprehensive Compliance
22 Program within six months of any update or revision of the “Code
23 on Interactions with Health Care Professionals.”

24 (c) Each pharmaceutical company shall include in its
25 Comprehensive Compliance Program limits on gifts or incentives
26 provided to medical or health professionals, in accordance with
27 this chapter.

28 (d) (1) *Each pharmaceutical company shall establish*
29 *explicitly in its Comprehensive Compliance Program a specific*
30 *annual dollar limit on gifts, promotional materials, or items or*
31 *activities that the pharmaceutical company may give or otherwise*
32 *provide to an individual medical or health care professional in*
33 *accordance with the “Compliance Program Guidance for*
34 *Pharmaceutical Manufacturers” and with the “Code on*
35 *Interactions with Health Care Professionals.”*

36 (2) *Notwithstanding paragraph (1), drug samples given to*
37 *physicians and healthcare professionals intended for free*
38 *distribution to patients, financial support for continuing medical*
39 *education forums, and financial support for health educational*
40 *scholarships are exempt from any limits if that support is provided*

1 in a manner that conforms to the “Compliance Program Guidance
2 for Pharmaceutical Manufacturers” and the “Code on
3 Interactions with Health Care Professionals.”

4 (3) Payments made for legitimate professional services
5 provided by a health care or medical professional, including, but
6 not limited to, consulting, are exempt from any limits, provided that
7 the payment does not exceed the fair market value of the services
8 rendered, and those payments are provided in a manner that
9 conforms to the “Compliance Program Guidance for
10 Pharmaceutical Manufacturers” and with the “Code on
11 Interactions with Health Care Professionals.”

12 (e) The pharmaceutical company shall annually acknowledge
13 certify, in writing, that it is in compliance with both its
14 Comprehensive Compliance Program and this chapter. A
15 pharmaceutical company shall make its Comprehensive
16 Compliance Program and its written acknowledgment of
17 compliance with the program and this chapter available for public
18 inspection upon request.

19 ~~(e) The pharmaceutical company shall make its~~
20 ~~Comprehensive Compliance Program and its annual written~~
21 ~~certification of compliance with the program available to the~~
22 ~~public on the pharmaceutical company’s Web site and shall also~~
23 ~~provide a toll-free telephone number where a copy or copies of the~~
24 ~~Comprehensive Compliance Program and written certification of~~
25 ~~compliance may be obtained.~~

26 (f) Nothing in this section shall be construed to create a
27 standard for a pharmaceutical company that is less restrictive than
28 any otherwise applicable provision of law.

29 (g) This section shall become operative on July 1, 2005.

30 119404. ~~(a) A pharmaceutical company may not give gifts to~~
31 ~~medical or health professionals, except for the following:~~

32 ~~(1) Professional samples of a drug intended for free~~
33 ~~distribution to patients.~~

34 ~~(2) Educational materials.~~

35 ~~(3) Items primarily associated with a health care professional’s~~
36 ~~practice, including, but not limited to, pens, pads, and tissue boxes,~~
37 ~~as long as the value of each item does not exceed five dollars (\$5).~~

38 ~~(b) Payments made for legitimate professional services~~
39 ~~provided by a health care or medical professional, including, but~~
40 ~~not limited to, consulting, are not considered gifts for purposes of~~

- 1 ~~this chapter, provided that the payment does not exceed the fair~~
2 ~~market value of the services rendered.~~
3 ~~(c) The total value of all gifts received by a medical or health~~
4 ~~professional from a pharmaceutical company may not exceed~~
5 ~~three hundred forty dollars (\$340) in any calendar year.~~

